

REMARKS

This Response, filed in reply to the Office Action dated July 2, 2009, is believed to be fully responsive to each point of objection and rejection raised therein. Accordingly, favorable reconsideration on the merits is respectfully requested.

Claims 9 and 11-18 are currently under examination on the merits, and are rejected. No new matter is added by way of this Response. Consideration of the remarks herein is respectfully requested.

Withdrawn Rejections

Applicants thank the Examiner for withdrawal of the rejection of Claims 9 and 11-18 under 35 U.S.C. §103(a) as set forth in the Office Action mailed February 26, 2009, in view of Applicants' remarks submitted in the Response filed May 6, 2009.

Claims 9 and 11-18 are Patentable Under 35 U.S.C. § 103(a)

On page 2 of the Office Action, Claims 9 and 11-18 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Clausen *et al.* (U.S. Patent No. 5, 563,040) in view of Hirano *et al.* (*Journal of Wood Science*, 2000, 46:45-51), both of record, and further in view of Khowala *et al.* (U.S. Patent No. 6,946,277).

In making the rejection, the Examiner contends that Clausen *et al.* discloses an agent for diagnosing wood decay, comprising a monoclonal or polyclonal antibody obtained by sensitizing an animal with a protein obtained by culturing a wood destroying fungus, namely *Postia placenta*. The Examiner further contends that Clausen *et al.* discloses the fungi *Gloeophyllum trabeum*, *Coniophora puteana* and *Serpula* sp., citing column 7, and a diagnostic kit having a

polyester cloth device and a capture zone for the substrate. However, the Examiner acknowledges that Clausen *et al.* does not disclose raising an antibody against a protein fraction having a molecular weight range of 1000-100,000 Daltons, and wherein the protein fraction is extracted from a species recited in Claim 9.

The Examiner again relies upon Hirano *et al.* in an attempt to rectify the deficiencies of Clausen *et al.*, contending that Hirano *et al.* discloses the extraction of a low molecular weight protein fraction from cultures of *Tyromyces palustris* (*i.e. Fomitopsis palustris*), citing the Abstract. The Examiner further contends that Hirano *et al.* discloses immunoblotting and ELISA using antibodies raised against this fraction. However, the Examiner acknowledges that neither Clausen *et al.* nor Hirano *et al.* disclose the use of cellobiose as a main carbon source for culturing *T. palustris*. In an attempt to rectify the deficiencies of Clausen *et al.* and Hirano *et al.*, the Examiner newly cites to Khowala *et al.*, alleging that Khowala *et al.* discloses cellobiose as “the main carbon source for culturing wood decaying fungi,” citing column 5, lines 27-45, and Claim 2.

From the above references, the Examiner takes the position that one of ordinary skill in the art would readily have cultured the fungus of Hirano *et al.* using cellobiose as the main carbon source, and subsequently used the purified protein fraction of Hirano *et al.* to produce an antibody to be used in the method of Clausen *et al.* The Examiner again relies on column 5 of Clausen *et al.* to allege that one of ordinary skill in the art would have possessed sufficient motivation to combine the alleged prior art elements in the manner claimed by Applicants, because Clausen *et al.* allegedly discloses that “numerous modification[s] and embodiments devised by those skilled in [the] art other [than] the ones specifically described above, may be employed to detect the presence of the suspected antigens.”

Applicants respectfully disagree, and traverse the rejection in view of the following.

The Office Action fails to set forth a reason that would have prompted a person of ordinary skill to culture the fungi of Hirano *et al.* in a medium containing cellobiose as the main carbon source.

First, Applicants again respectfully point out that relevant law holds that it is necessary to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). Further still, a *prima facie* case of obviousness cannot be maintained if one of ordinary skill in the art would not have possessed at least a reasonable expectation of success in making such a combination.

In this regard, Applicants respectfully submit that the outstanding obviousness rejection over Clausen *et al.*, Hirano *et al.* and Khowala *et al.* suffers from the same deficiencies as the previous rejection of record over Clausen *et al.*, Hirano *et al.* and Kawai *et al.*, namely in that the rejection fails to proffer a reason that would credibly have prompted a person of ordinary skill in the relevant field to culture the fungi of Hirano *et al.* in a medium in which cellobiose is the main carbon source. Specifically, as acknowledged by the Examiner, column 5 of Clausen *et al.* provides merely a *generic* suggestion that “numerous modifications and embodiments devised by those skilled in the art, other than the ones described above, may be employed to detect the presence of the suspected antigen.” However, this generic suggestion, in itself, clearly provides no credible reason or motivation that would have prompted a person of ordinary skill in the relevant field to use cellobiose as the major carbon source in the method of Hirano *et al.*, as is required to sustain the rejection. Indeed, while the Examiner attempts to impart some specificity to this portion of Clausen *et al.* by referring to the proceeding sentence, wherein Clausen *et al.*

contemplates the use of antibodies to other fungal components, or to other groups of fungi, Applicants point out that this disclosure is equally deficient, providing no reason or motivation that would have prompted one of ordinary skill in the art to use cellobiose as the major carbon source in the method of Hirano *et al.*

In view of the foregoing, Applicants respectfully submit that a *prima facie* case of obviousness has not been established at least because the rejection fails to proffer a reason that would have prompted a person of ordinary skill in the relevant field to culture the fungi of Hirano *et al.* in a medium containing cellobiose as the main carbon source. Because no such reason has been provided, the rejection cannot be sustained. See *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). Moreover, absent such a credible reason, it is clear that the rejection is firmly grounded in impermissible hindsight reconstruction, relying solely upon Applicants' disclosure to bridge the gap between the reference disclosures and the claimed invention.

In view of the unrelated disclosures of Hirano *et al.* and Khowala *et al.*, one of ordinary skill would not have possessed sufficient motivation to combine the cited references.

Second, and independent of the above arguments, Applicants respectfully submit that one of ordinary skill in the art would not have possessed sufficient reason or motivation to employ a medium containing cellobiose as the major carbon source in the method of Hirano *et al.*, in view of the substantially disparate disclosures of Hirano *et al.* and Khowala *et al.*

For example, in the portion of Khowala *et al.* relied upon to make the rejection, namely column 5, lines 27-45, Khowala *et al.* discloses the use of D-cellobiose with succinate as a main carbon source for culturing *Termitomyces clypeatus* **solely** for the purpose of enhancing the

secretion of cellobiase into the culture medium; as discussed in column 6, lines 23-28, cellobiose is employed because it produces high cellobiase activity in the culture medium when a glycosylation inhibitor (*i.e.*, 2-deoxy-D-glucose) is also present. In contradistinction however, enhanced cellobiase activity is irrelevant to the method of Hirano *et al.*; Hirano *et al.* is directed to the production of antibodies against low-molecular weight peptides that catalyze the production of hydroxyl radicals, which hydroxyl radicals are involved in wood cell wall degradation. The rejection has failed to even suggest, much less establish, any relevant connection between cellobiase activity and the low-molecular weight proteins of Hirano *et al.*, such that one of ordinary skill in the art would have possessed even a scintilla of motivation to make such a modification. Accordingly, Applicants respectfully submit that the presently claimed invention is not rendered obvious also because, in view of the unrelated and disparate disclosures of Hirano *et al.* and Khowala *et al.*, one of ordinary skill in the art would not have possessed sufficient motivation to combine the disclosures of Hirano *et al.* and Khowala *et al.*

One of ordinary skill in the art would not have possessed a reasonable expectation of success in modifying the method of Hirano *et al.* to use cellobiose as the main carbon source.

Third, and independent of the above arguments, Applicants respectfully submit that the presently claimed invention is nonobvious over the cited references at least because one of ordinary skill in the art would not have possessed a reasonable expectation of success in employing cellobiose as the main carbon source in the method of Hirano *et al.*, as is required of obviousness. For example, in the paragraph bridging columns 1 and 2 of page 45, Hirano *et al.*, citing to Enoki *et al.* as support, states that “the rates of [hydroxyl radical] production in cultures of brown-rot fungi, including *Tyromyces palustris*, are directly proportional to the degradation

rates of wood, crystalline cellulose, and lignin substructure model compounds.” (Emphasis added.) Enoki *et al.*¹ demonstrates the inducibility of these hydroxyl radicals, through the inducibility of the low-molecular weight proteins of Hirano *et al.*, in response to specific substrates. For example, Enoki *et al.*, using ethylene production as an indicator of oxidant production, discloses that if *T. palustris* is cultured in a medium using glucose as a carbon source, or glucose in combination with either lignin or cellulose, neither cellulose or lignin degradation occurs, nor does ethylene production (see Table 2), demonstrating that hydroxyl production is not induced in these samples; Table 3 directly confirms the correlation between hydroxyl radical production by *T. palustris* (the focus of Hirano *et al.*) and ethylene production, because ethylene production by *T. palustris* was markedly suppressed by the addition of the hydroxyl radical scavengers DMNA and guaiacol.

In contrast, however, as demonstrated in Table 2 of Enoki *et al.*, oxidant production by *T. palustris* was only induced when beech wood was present in the culture medium, suggesting that the low-molecular weight proteins catalyzing hydroxyl radical production are specifically induced in the presence of only wood, and not glucose, lignin or cellulose. It is well-settled that in any obviousness inquiry, the person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention. See *In re GPAC*, 57 F.3d 1573, 1579, 35 USPQ2d 1116, 1121 (Fed. Cir. 1995); *Custom Accessories, Inc. v. Jeffrey-Allan Industries, Inc.*, 807 F.2d 955, 962, 1 USPQ2d 1196, 1201 (Fed. Cir. 1986) and; *Environmental*

¹ In accordance with M.P.E.P. 609(c), the documents cited herein in support of Applicants’ remarks are being submitted as evidence directed to an issue raised in the Official Action, and no fee pursuant to 37 C.F.R. 1.97 or 1.98, or citation on a FORM PTO/SB/08 or PTO-1449 is believed to be necessary.

Designs, Ltd. V. Union Oil Co., 713 F.2d 693, 696, 218 USPQ 865, 868 (Fed. Cir. 1983).

Certainly, in view of the fact that Hirano *et al.* directly cites to Enoki *et al.* in the context of hydroxyl radical production by *T. palustris*, and its role in wood, crystalline cellulose, and lignin degradation, it is clear that Enoki *et al.* would have been relevant, and thus known, to one of ordinary skill in the pertinent art reading Hirano *et al.* In view of the foregoing, Applicants respectfully submit that one of ordinary skill in the art, who is presumed to have known the relevant art at the time of the invention (and thus would have known the teachings of Enoki *et al.*), would not have possessed a reasonable expectation of success in modifying the method of Hirano *et al.* to use cellobiose as the main carbon source, because they would readily have appreciated that the sawdust in the culture of Hirano *et al.* (which is the main carbon source, because 2g of sawdust was used per 30 ml culture vis-à-vis only 0.15g (0.5%) of glucose) is *critical* for induction of synthesis of the low-molecular weight peptides catalyzing hydroxyl radical production (given that Enoki *et al.* demonstrates that hydroxyl radical production is not induced with glucose, or glucose in combination with lignin or cellulose, but specifically requires wood, indicating these proteins are not produced under such conditions).

Accordingly, Applicants respectfully submit that the presently claimed invention is not rendered obvious over the cited references at least because one of ordinary skill in the art would not have possessed any expectation of success in modifying the method of Hirano *et al.* to use cellobiose as the main carbon source. Clearly, with such a lack of expectation of success also follows a lack of motivation to arrive at the presently claimed invention.

Replacing the main carbon source of Hirano *et al.*, namely, sawdust, with cellobiose, would preclude production of the low-molecular weight peptides, thus modifying the

principle of operation of the method of Hirano *et al.*, and rendering it unsatisfactory for its intended purpose.

Fourth, and independent of the above arguments, Applicants respectfully point out that, as evidenced by Enoki *et al.*, the modification of the method of Hirano *et al.* asserted in the rejection would change the principle of operation of the method of Hirano *et al.*, and render it unsatisfactory for its intended purpose, both of which preclude a finding of obviousness. Specifically, the method of Hirano *et al.* relied upon to sustain the rejection is the production of antibodies against low-molecular weight peptides catalyzing hydroxyl radical production. However, as described above, Enoki *et al.* demonstrates the criticality of wood in the culture medium for production of the low-molecular weight peptides of Hirano *et al.* catalyzing hydroxyl radical formation. As such, substituting the main carbon source of Hirano *et al.*, *i.e.*, sawdust, with cellobiose, as asserted in the rejection, would preclude production of the low-molecular weight peptides of Hirano *et al.*, thus modifying the principle of operation of the method of Hirano *et al.*, and rendering it unsatisfactory for its intended purpose.

For all the foregoing reasons, Applicants respectfully submit that the presently claimed invention is nonobvious, and patentable, over the cited references.

Withdrawal of the rejection is respectfully requested.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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